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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/453,109	12/02/1999	MARK R. PRAUSNITZ	BVTP-P01-539	2183
28120	7590	08/07/2006	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			WINAKUR, ERIC FRANK	
			ART UNIT	PAPER NUMBER
			3768	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/453,109	PRAUSNITZ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Eric F. Winakur	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20-22 and 24-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47-55 is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-12, 14-18, 20-22, 24, 25 and 27-46 is/are rejected.
- 7) ☒ Claim(s) 8, 9, 13 and 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 102***

2. The rejection of claims 1, 2, 12, 14, 15, 18, 20, 22, 25, 27, 28, 31, 32, 36, 37, 40, 41, and 44 - 46 under 35 U.S.C. 102(b) as being anticipated by Lin et al. is hereby maintained for the reasons of record.

#### ***Claim Rejections - 35 USC § 103***

3. The rejection of claims 1 - 4, 6, 7, 10, 15, 27, 29 - 34, 36, and 40 under 35 U.S.C. 103(a) as being unpatentable over Yoshihiko in view of Lin et al. is hereby maintained for the reasons of record.

4. The rejection of claims 1, 2, 11, 14 - 17, 20, 21, 24, 27, 28, 30 - 32, 35 - 37, 40, 41, and 44 - 46 under 35 U.S.C. 103(a) as being unpatentable over Smart et al. in view of Lin et al. is hereby maintained for the reasons of record.

#### ***Double Patenting***

5. Claims 8, 9, 13, and 26 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 53. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Response to Arguments***

6. Applicant's arguments filed 5 July 2006 have been fully considered but they are not persuasive. Applicant contends that the teaching of Lin et al. does not meet the claimed subject matter because Lin et al. does not teach a "microneedle" having a length in the claimed range. Applicant bases this assertion on the description given in Lin et al. that refers to the entire device as a "microneedle". It is noted that Applicant has chosen to use the term "microneedle" to refer to a shaft portion of their claimed device and to draw their claim to a "device for collecting a sample" that includes a microneedle as one of its elements. Claim analysis involves a comparison of the claimed structure with the disclosed structure of the prior art, not a comparison of the choice of terms used by Applicant and the prior art to describe their respective inventions. Applicant's claimed "microneedle" is a shaft portion of their device, which corresponds to the "hollow shaft" having length "y" of the device of Lin et al. As detailed in the previous Office action, Lin et al. disclose that this element has a length between 1 - 6 mm, and further disclose the other claimed elements of the device, thereby meeting Applicant's claimed structure. As such, the rejection is proper and is hereby maintained.

7. With regard to the rejections under 35 U.S.C. 103(a), Applicant merely contends that the combinations fail to meet the claim limitations for the same reasons as given in the arguments against Lin et al. As these arguments were not found persuasive for the reasons given above, the rejections under 35 U.S.C. 103(a) are also maintained.

***Allowable Subject Matter***

8. Claims 47 - 55 are allowed.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

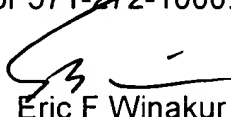
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571/272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Eric F Winakur  
Primary Examiner  
Art Unit 3768